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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,820	02/19/2002	Todd K. Whitehurst	AB-116U	3079

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EXAMINER	
BOCKELMAN, MARK	
ART UNIT	**PAPER NUMBER**
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/081,820	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,14-16,36-38 and 41* is/are pending in the application.

4a) Of the above claim(s) *36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-5, 8, 14-16, 38 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11-24-2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-6-2007 has been entered.

Specification

The disclosure is objected to because of the following informalities: Applicants need to update the status of serial number 09/624,130 as cited on page 11 line 27 of their specification. It would appear the application is abandoned.

Appropriate correction is required.

Election/Restrictions

Claims 36 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2-9-2005. The examiner notes that claim 36, which includes the pharyngeal and laryngeal branches of the vagus nerve, appear to be limited to the treatment of sleep disorders, paragraph [0081] of applicant's specification, and not to the treatment of headaches which was the invention elected by applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant claims a range for defining an upper and lower boundary. The boundary is indefinite. For instance, it is unclear as to whether the value of 75 Hz is included or excluded in the recited ranges.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 8, 14-16, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al USPN 6,164,284 in view of Terry, Jr USPN 5,215,086 or vice versa. As noted in the previous office actions Schulman teaches a leadless micro-stimulator with electrodes 112 for nerve stimulation (column 1, lines 15-21) in response to sensor detection of body conditions. The device has a stimulation control unit that may be positioned in the body and activated by implanted sensors or may be placed outside the body for patient control. Sensors may be built into each device so that they may act as either stimulators and or sensing devices. Applicant differs from the

teachings of Schulman et al in reciting methods using micro-stimulators of the Schulman type construction, to stimulate the vagus nerve to treat a wide variety of illnesses including headaches, the elected invention. Terry USPN 5,215,086 teaches a method of treating migraine headaches by stimulating the vagus nerve using an implantable stimulator which may include implanted sensors or may be activated by and external controller (column 12 lines 47-69). Terry teaches a stimulation frequency range of 5-150 Hz for treating the patient (see table in column 11). To have used the neural stimulator of Schulman et al in the Terry method would have been obvious since the Schulman device is designed for stimulation and offers a compact stimulator that may delivered by an injector reducing the amount of surgery needed for implantation.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al USPN 6,164,284 in view of Terry, Jr USPN 5,215,086 or vice versa as applied to claims 1, 5, 8, 14, 15, 16, 38 and 41 above, and further in view of Zabara USPN 4,867,164.

Applicant differs from the combined teachings of Schulman et al and Terry, Jr et al. in reciting that the positioning of the stimulator along the vagus nerve in "distal" to several of the cardiac branch nerves along the vagus nerve. It has long been recognized that simulation for a variety can be accomplished by the appropriate stimulation of the vagus nerve and while any point along the nerve may be selected for stimulation, stimulation is best accomplished when positioned below the inferior cardiac nerve to avoid slowing of the heart as taugh in Zabara (column 7, lines 4-10) Since a

physician who is treating a migraine headache would not necessarily want to stimulate the heart and slow it down, it would have been obvious to place the Schulman et al device below the inferior cardiac nerve (which is below the superior branch) as well as all cardiac nerve branches including the thoracic branch.

Claims 1-5, 8, 14-16, 38 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bion™ , applicant's admitted prior art see table on page 10 of specification or alternatively over Schulman et al USPN 6,164,284 each reference in further view of any one of Wernicke et al USPN 5,231,988 (Endocrine, metabolic disorders), Zabara USPN 4,867,164 (epilepsy) Bojeva USPN 6,356,788 (mood disorders), Rutecki et al. USPN 5,330,515 (chronic pain / anxiety), Terry, Jr USPN 5,707,400 (hypertension), Terry, JR et al USPN 5,540,730 (gastrointestinal), Wernicke et al USPN 5,269,303 (dementia), Wernicke et al USPN 5,188,104 (obesity/eating disorders), Wernicke et al USPN 5,299,569 (neuropsychiatric disorders) Terry, Jr et al USPN 5,335,657 (sleep disorder), Terry, Jr et al. USPN 5,540,730 (motility disorder) or Terry, Jr USPN 6,622,041 (cardiac disorder).

Applicant uses devices known in the art to provide leadless stimulation to nerve tissue as noted on page 10 of their specification. Applicant's claims recite vagus neural stimulation using these devices to treat various illnesses. Each of the the treatment methods is a known vagus simulation treatment method. To have provided the vagus neural stimulation disclosed in each of the secondary references with old and well known microstimulators would have been obvious to one or ordinary skill in the art.

Response to Arguments

Applicant's arguments filed 3-6-2007 have been fully considered but they are not persuasive. Applicants argue that the examiner has erred in combining the various references applied due to a lack of motivation, a teaching away by the secondary references and a lack of reasonable expectation of success.

Firstly, the Schulman devices as well as the Bion™ are well known neural stimulation devices. They are designed to stimulate nerves to produce therapeutic results. The secondary references are methods of stimulating nerves to produce therapeutic desired results. The examiner cannot think of a stronger motivation to combine reference than to select a known a device that is designed for a specific treatment (nerve stimulation) and apply it to methods for which it is designed. The examiner cannot understand how much more motivation is needed. However, there are additional obvious benefits such as size, and ease of implantation with the primary references that even more so provide motivation.

Secondly, the applicants have argued that there is some sort of teaching of away by each of the secondary references and they base this argument on the Adkin secondary reference. While the examiner does not quite understand the position, that particular reference has been dropped from the rejection in lieu of better teachings. The other rejections have not been dropped and new ones are added to cover each and every one the treatments specified in the base claims. Applicant has not addressed any of the remaining combinations for the "teaching away" aspect of his arguments. The

examiner apologizes for the large number of rejections, but the scope of the claims is quite broad and the examiner wants to cover all bases. As a result there are now 11 primary references and 12 secondary references making for 132 possible combinations. If applicant intends to pursue the breadth of these claims with "teaching away" arguments, applicant needs to address each and every one of these rejections in the next response so as to be fully responsive to the office action.

Thirdly, applicant is cautioned about critiquing the examiner's rejections as improper, "obvious to try" combinations, and arguing there is no reasonable expectation of success when applicant's own specification provides nothing additional than a laundry lists of micro-stimulators and treatment applications. The test of reasonable expectation for success applies to enablement of application specifications as well. Applicant shows no working examples, and no results. In many of the dependent claims the applicant claims items such as feedback sensors to aid in the treatment. The applicant has elected the method of Headache treatments and none of the description in the specification teaches how to use the sensor for such a treatment. Applicants' specification merely states generalized sensors [0057] may be provided on the stimulators when needed, but does not teach how to use any of them for treating a headache. However, it is considered by the examiner at this time, that there is some suggestion that one may be used and because of the prior art, that one could figure out to use the sensor.

The examiner is confounded by the double standard the applicants wish to impose on the examiner. While applicants show know working examples or results in

their specification and instead merely propose the use of the known stimulators to treat the known conditions, the applicants argue that there is no reasonable expectation of success for the examiner stating that the references would suggest the same. How can this be? The examiner notes the words of wisdom from the CCPA that applicants own specification can not be used as a measure of reasonable expectation of success and in general this would be the case but when the examiner is relying the same devices and methods as the proposals in applicant's specification, which is unsupported by working results and provides for no unexpected results, the examiner believes the quotation is not applicable. If applicants wish to list the reasons why the Bion™ wouldn't expect to work or the Schulman device as well, the examiner wishes to see them. Applicants have stated none at this time. There is no reason to not expect these devices to work as proposed by the examiner. The Bion™ and Schulman devices are designed to stimulated nerves and one would expect they to work for any nerve to be stimulated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Carl Layno can be reached on (571) 272 -4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mark Bockelman

March 16, 2007